THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today

- (1) was not written for publication in a law journal and
- (2) is not binding precedent of the Board.

Paper No. 30

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte LEE R. BECK and RALPH J. STOLLE

Appeal No. 94-3222 Application $07/815,630^{1}$

HEARING: July 16, 1998

¹ Application for patent filed December 30, 1991. According to applicants, this application is a continuation of Application 07/548,419, filed July 5, 1990, now abandoned; which is (1) a continuation-in-part of Application 07/431,639, filed November 6, 1989, now U.S. 5,130,128, issued July 14, 1992; and (2) a continuation-in-part of Application 07/177,223, filed April 4, 1988, now U.S. 4,956,349, issued September 11, 1990. Application 07/431,639 is a continuation-in-part of Application 07/161,039, filed February 26, 1988, now U.S. 4,879,110, issued November 7, 1989. Both Applications 07/161,039 and 07/177,223 are continuations-in-part of Application 07/001,848, filed January 9, 1987, now U.S. 4,897,265, issued January 30, 1990; which is a divisional of Application 06/546,162, filed October 27, 1983, now U.S. 4,636,384, issued October 23, 1990; which is a continuation-in-part of Application 06/384,625, filed June 3, 1982, now abandoned. U.S. 4,636,384 was reissued as U.S. Re. 33,403 on October 23, 1990.

Before WINTERS, WILLIAM F. SMITH, and GRON, <u>Administrative</u> <u>Patent Judges</u>.

GRON, Administrative Patent Judge.

DECISION ON APPEAL UNDER 35 U.S.C. § 134

This is an appeal under 35 U.S.C. § 134 from an examiner's final rejection of Claims 2 and 6-9.

On consideration of the record of this case in its entirety, it is hereby ORDERED that

the examiner's final rejections in this case are VACATED, and that

this application is REMANDED to the examiner for further action consistent with the following opinion.

1. Introduction

Claims 1-9 are pending in this application. In accordance with 37 CFR § 1.142(b), Claims 1 and 3-5 have been withdrawn from further consideration by the examiner as directed to non-elected subject matter under a restriction requirement. Claims 2 and 6-9 stand rejected as unpatentable under 35 U.S.C. § 101 purportedly as drawn to subject matter without practical utility and under

35 U.S.C. § 112, first paragraph, as supported by a specification which purportedly would not have enabled persons skilled in the art to use the full scope of products and methods claimed for the utility indicated.

According to appellants, Claims 2 and 6-9 stand or fall together (Brief on Appeal, p. 4). Claims 2 and 6 represent the subject matter claimed and read:

2. A food product comprising a composition wherein said composition comprises a non-antibody fraction of milk

and wherein said non-antibody fraction of milk ameliorates,

in a subject with an allergy to an allergen, the symptoms of said allergy of said subject to said allergen when said

fraction is ingested by said subject and wherein said fraction is produced by the process comprising:

- (a) administering said allergy to a milkproducing animal;
- (b) collecting the milk from said animal of
 part (a);
- (c) filtering the milk of part (b) through
 a filter which excludes molecules of greater than
 100,000 daltons; and
- (d) collecting the effluent from the filtration of part (c) wherein said effluent contains said fraction.
- 6. A method for desensitizing a subject to an allergen wherein said method comprises orally administering to said subject a food product, in an amount and for a time

sufficient to produce an amelioration in said subject of

symptoms of allergy to said allergen, wherein said food product comprises a non-antibody fraction of milk from a milk-producing animal that has been immunized with said allergen.

2. Discussion

It should have been apparent from the questions this panel of the Board asked counsel at Oral Hearing on July 16, 1998, that we should not rule on the merits of this appeal because, as a matter of law, it would be incorrect to do so. Accordingly, we vacate the examiner's decision finally rejecting the subject matter on appeal under 35 U.S.C. § 101 and under 35 U.S.C. § 112, first paragraph, for reasons which follow.

We have searched the record of this case and do not find any indication that the metes and bounds of the subject matter claimed have been established. Where, as here, the issues presented for our review concern the practical utility of the full scope of the subject matter claimed and the specification's capacity to enable one skilled in the art to make and use the full scope of the subject matter claimed, claim interpretation is a necessary prerequisite to resolution of the merits of the issues presented. See In re Steele, 305 F.2d 859, 862, 134 USPQ 292, 295 (CCPA 1962) (When an analysis

of the claims leaves the reviewing body in a quandary as to what they cover, the examiner and the Board may not rely on speculation as to the meaning of the claims in support of a rejection.) In re Moore, 439 F.2d 1232, 169 USPQ 236 (CCPA 1971) instructs at 1235, 169 USPQ at 238 [footnotes omitted]:

[The] . . . first inquiry therefore is merely to determine

whether the claims do . . . set out and circumscribe a particular area with a reasonable degree of precision and particularity. It is here where the definiteness of the language employed must be analyzed--not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art.

Once having determined that the subject matter defined by the claims is particular and definite, the analysis then turns to the first paragraph of section 112 to determine whether the scope of protection sought is supported and justified by the specification disclosure.

For example, the examiner appears not to have interpreted the term "allergen" in Claims 2 and 6, the phrases "allergy to an allergen" in Claim 2 and "allergy to said allergen" in Claim 6, the phrases "ameliorates . . . the symptoms of said allergy" in Claim 2 and "an amelioration . . . of symptoms of allergy" in Claim 6, the term "non-antibody fraction" in Claims 2 and 6, the phrase "a non-antibody fraction of milk from a milk-producing animal that has been immunized with said

allergen" in Claim 6 (emphasis added), and the phrase "excludes molecules of greater than 100,000 daltons" in Claim 2. We will refrain from considering the patentability of the claimed subject matter under 35 U.S.C. § 101 and under 35 U.S.C. § 112, first paragraph, until the examiner has first interpreted the meaning and breadth of the aforementioned terms and phrases in light of the description of the claimed subject matter in the specification and the teachings of the prior art. Id. at 1235, 169 USPQ at 238.

Moreover, we do not understand how it is possible for the examiner of this application to consider the meaning and breadth of the terms and phrases in appellants' claims in light of the prior art or to determine whether this specification would have enabled persons skilled in the art at the pertinent time to make and use the full scope of invention claimed without having first determined the effective filing date of the subject matter claimed. Unless and until the effective filing date of the subject matter presently claimed is established, what is and what is not prior art as to the subject matter presently claimed can be no more than speculative.

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For example, applicants claim the benefit of priority under 35 U.S.C. § 120 through two lineages (Spec., p. 1, first para.):

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(1)07/815,630
              December 30, 1991
                      Π
               (continuation)
               (2)07/548,419
                July 5, 1990
(continuation-in-part)
        (3)07/431,639
         (November 6, 1989) (continuation-in-part)
                \prod
                                    (5)07/177,223
(Continuation-in-part)
                            (April 4, 1988)
     (4)07/161,039
  (February 26, 1988)
                 (continuation-in-part)
                (6)07/001,848
              (January 9, 1987)
                       N
                               (divisional)
                 (7)06/546,162
              (October 27, 1983)
            (continuation-in-part)
                (8)06/384,625
                (June 3, 1982)
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With those two lines in mind, we list the following information:

- (1) Application 07/815,630 for "IMMUNE SUPPRESSIVE PRODUCT," was filed December 30, 1991, in the names of Beck and Stolle.
- (2) Application 07/548,419 was filed July 5, 1990, also in the names of <u>Beck and Stolle</u> and is said to be the parent of continuation Application 07/815,630 (this application);
- (3) Application 07/431,639 for "USE OF HONEY AS VACCINE" was filed November 6, 1989, in the sole name of <u>Stolle</u> and issued July 14, 1992, as U.S. 5,130,128;
- (4) Application 07/161,039 for "ANTIHYPERTENSIVE HYPERIMMUNE MILK, PRODUCTION, COMPOSITION, AND USE" was filed February 26, 1988, in the names of <u>Beck and Stolle</u> and issued November 7, 1989, as U.S. 4,879,110;
- (5) Application 07/177,223 for "ANTI-INFLAMMATORY FACTOR, METHOD OF ISOLATION, AND USE" was filed April 4, 1988, in the sole name of Beck and issued September 11, 1990, as U.S. 4,956,349;
- (6) Application 07/001,848 for "METHOD FOR TREATING DISORDERS OF THE VASCULAR AND PULMONARY SYSTEMS" was filed January 9, 1987, in the names of <u>Stolle and Beck</u> and issued January 30, 1990, as U.S. 4,897,265;

- (7) Application 07/546,162 for "METHOD FOR TREATING DISORDERS OF THE VASCULAR AND PULMONARY SYSTEMS" was filed October 27, 1983, in the names of <u>Stolle and Beck</u> and issued January 13, 1987, as U.S. 4,636,384; and
- (8) Application 07/384,625, now abandoned, was filed June 3, 1982, in the names of <u>Stolle and Beck</u>.

We note from the above listing that while the subject matter appellants claim appears to be entitled to the July 5, 1990, filing date of (2) Application 07/548,419 filed in the names of <u>Beck and Stolle</u> as a file-wrapper continuation of this application, it is not at all apparent that the full scope of the subject matter presently claimed is entitled either to the November 6, 1989, filing date of (3) Application 07/431,639 for "USE OF HONEY AS VACCINE" filed in the sole name of Stolle or the April 4, 1988, filing date or (5) Application 07/177,223 for "ANTI-INFLAMMATORY FACTOR, METHOD OF ISOLATION, AND USE" filed in the sole name of Beck. fact, this record is noticeably devoid of any indication that the effective filing date of the subject matter claimed has been determined. Accordingly, it is our view that claim interpretation in light of the prior art cannot have been adequately done without first determining the merits of

applicants' claims under 35 U.S.C. § 120 so as to enable one to establish what constitutes the prior art under 35 U.S.C. § 102.

Moreover, while compliance with the requirements of 35 U.S.C. § 112, first paragraph, is normally determined as of the filing date of the pending application, the examiner, when faced with an intervening reference, may be required to focus on the filing date of a prior application as the result of the applicants' claims for priority under 35 U.S.C. § 120. United States Steel Corp. v. Phillips Petroleum Co., 865 F.2d 1247, 1251, 9 USPQ2d 1461, 1464 (Fed. Cir. 1989). We appear to have just such a case before us.

On their face, Stolle, U.S. 5,130,128, filed November 6, 1989, and Beck, U.S. 4,956,349, filed April 4, 1988, appear to be prior art under 35 U.S.C. § 102(e) whether or not they are commonly assigned with this application filed in the names of Beck and Stolle. See In re Bartfeld, 925 F.2d 1450, 17 USPQ2d 1885 (Fed. Cir. 1991). Moreover, Stolle and Beck, U.S. 4,636,384 and U.S. 4,732,757 may be prior art under 35 U.S.C. § 102(b). Accordingly, faced with what prima facie appears at least in part to be prior art of record and applicants' claims for priority under 35 U.S.C. § 120 in this case, the examiner

should determine the effective filing date of the subject matter here claimed before ruling on patentability under either 35 U.S.C. § 112, first paragraph, § 101, § 102, or § 103. It is as of the effective filing date that compliance with 35 U.S.C. §§ 112, first paragraph, and 101 and prior art availability must be determined.

Only after determining the effective filing date of the subject matter claimed may the examiner (1) determine whether appellants' claims satisfy 35 U.S.C. § 112, second paragraph, in light of applicants' disclosure and the prior art, (2) consider whether the subject matter claimed is patentable under 35 U.S.C. § 101 or whether applicants' disclosure would have enabled one skilled in the art to make and use the full scope of the claimed subject matter as required by 35 U.S.C. § 112, first paragraph, (3) determine patentability under 35 U.S.C. §§ 102 and 103 in view of the prior art (compare Chester v. Miller, 906 F.2d 1574,

1576, 15 USPQ2d 1333, 1336 (Fed. Cir. 1990), citing <u>In re</u>

<u>Gosteli</u>, 872 F.2d 1008, 1010-1011, 10 USPQ2d 1614, 1616 (Fed. Cir. 1989)), and (4) determine whether the subject matter claimed in this case is unpatentable for obviousness-type

double-patenting of subject matter claimed in any one or more of the U.S. patents which have issued from applications for which

priority under 35 U.S.C. § 120 here is claimed.²

We will allow the examiner of this case to determine in the first instance the effective filing date of the subject matter claimed, the scope and content of the pertinent prior art, compliance with the requirements of the second paragraph of Section 112, compliance with Section 101 and the first paragraph of Section 112, and patentability of the claimed subject matter under 35 U.S.C. § 102, under 35 U.S.C. § 103, and over subject matter claimed in commonly assigned patents absent the filing of effective terminal disclaimers. For this panel to review the merits of the examiner's decision rejecting the claims on appeal under 35 U.S.C. § 101 and under 35 U.S.C. § 112, first paragraph, at this time without those preliminary determinations having been made by an examiner is

The examiner may wish to consider obviousness-type double-patenting issues. However, take note that if questions of obviousness-type double patenting of subject matter claimed in issued patents come to light, the examiner may want to consider whether adhering to unpatentability determinations under 35 U.S.C. § 101 or 112, first paragraph, for lack of utility is consistent with the presumption of validity of the patented subject matter.

inconsistent with our review function. See 35 U.S.C. § 7

("The Board . . . shall . . . review adverse decisions of examiners") Accordingly, we vacate the examiner's final rejections and remand the case to the examining corps for action consistent with this opinion.

This application, by virtue of its "special" status, requires an immediate action, M.P.E.P. § 708.01(d). It is important that the Board be informed promptly of any action affecting the appeal in this case.

VACATED and REMANDED

SHERMAN D. WINTERS)
Administrative Patent Judge)

WILLIAM F. SMITH) BOARD OF PATENT
Administrative Patent Judge) APPEALS AND
INTERFERENCES
)
TEDDY S. GRON)

Administrative Patent Judge)

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